US ERA ARCHIVE DOCUMENT

Magnitude of the Residue OPPTS 860.1500 DACO 7.4.1

PC Code: 128008 MRID: 45405112 Submission #2001-1027, 1036, 1043



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

## **MEMORANDUM**

Date:

July 2, 2003

Reviewers:

William T. Drew, Chemist

Reviewer

RAB2/HED (7509C)

R. Loranger Date: 8/15/0=

Richard A. Loranger Branch Senior Scientist RAB2/HED (7509C) Henri P. Bietlot, Chemist

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REAS, HED, PMRA

Section Head

FREAS, HED, PMRA

DP Barcode: D278386

Petition:

1F06313

Citation:

45405112 Versoi, P.; Adbel-Baky, S. (2000) The Magnitude of BAS 510 F Residues in Dry Bulb and Green Onions: Final Report: Lab Project Number: 2000/5207: 63894: 99171 (PA/1). Unpublished study prepared by BASF

Corporation. 55 pages.

Sponsor:

**BASF** Corporation

## **Background**

The information contained herein was compiled by Dynamac Corporation (20440 Century Boulevard, Suite 100, Germantown MD 20874), contractor, under the supervision of RAB2/HED. This DER has undergone secondary review by RAB2, and reflects current HED and Office of Pesticide Programs (OPP) policies. This DER has also been peer-reviewed by PMRA/Canada.

# **Executive Summary**

BASF Corporation has submitted field trial data on the representative crops, green and dry bulb onions, of the bulb vegetable crop group (Crop Group 3). Three green onion trials were conducted in Regions 6 (one trial in Texas) and 10 (two trials in California) and six dry bulb

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onion trials were conducted in Regions 1 (one trial in Pennsylvania), 6 (one trial in Texas), 8 (one trial in Texas), 10 (two trials in California), and 11 (one trial in Oregon). The number and location of the field trials satisfy the US-EPA's data requirements with respect to the geographic representation of residue data for the bulb vegetable crop group. The number and location of these trials does not satisfy the data requirements of the PMRA.

At each test location, the 70% WG formulation of BAS 510 F was applied six times as a foliar spray at ~0.3 lb ai/A/application (0.336 kg ai/ha/application), with 13½ to 15-day re-treatment intervals, for a total rate of 1.79-1.83 lb ai/A (2.00-2.05 kg ai/ha). Mature samples were collected at a 7-day post-treatment interval. In one dry bulb onion field trial, additional samples were collected at 0, 14, 21, and 28 days following treatment to evaluate residue decline.

At the applied total rate of 1.79-1.83 lb ai/A (2.00-2.05 kg ai/ha), the ranges of BAS 510 F residues in/on treated mature samples were: 1.06-2.94 ppm for green onions and 0.026-1.03 ppm for dry bulb onions. The residue decline data for dry bulb onion demonstrated that residues of BAS 510 F generally decreased with increasing PHIs but that the decline was not linear.

Residues of BAS 510 F in/on onions (green and dry bulb) were quantitated using a validated LC/MS/MS method (D9908), the data collection method for plant commodities. Storage stability data (refer to the DER for MRID 45405109) are available to support the 186 days (6.1 month) maximum storage interval for the samples analyzed.

Residue data from the current submission are acceptable to fulfill the EPA's crop field trial data requirements for the bulb vegetable crop group (Crop Group 3). The submitted residue trials do not meet the requirements set out by the PMRA. A total of four additional residue trials in dry bulb onions (2 trial carried out in zone 5 and two trials carried out in zone 5B) and 2 additional residue trial in green onions (one trial in each of 5 and 5B) are required. It should be noted that these trials are needed to support both the use of this chemical on this crop group but also to support the residue levels resulting in rotated crops from the use of this chemical in any crop.

## **GLP** Compliance

Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. No GLP deviations were reported which would impact the study results or their interpretation.

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## 1. Materials and Methods

## 1.1. Test Substance

Active Ingredient

Common Name:

Nicobifen, ISO proposed

**IUPAC Name:** 

2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide

CAS Name:

3-Pyridinecarboxamide, 2-chloro-N-(4'chloro[1,1'-biphenyl]-2-yl)-

CAS Number:

188425-85-6

Company Name:

BAS 510 F

Other Synonyms:

BASF Registry No. 300355

Chemical Structure:

# 1.2. Trial Locations

		Green (	Onions 1			Dry Bul	b Onions	1	7	N	/A	
NAFTA Growing	Cas	nada	ı	JS	Ca	nada	T	US	Car	nada	ī	IS
Region	SUB	REQ	SUB	REQ <sup>2</sup>	SUB	REQ	SUB	REQ	SUB	REQ	SUB	REQ
1							1	1	192			
0.04167												
2												
3												
4												
5	0	1			0	3						
0.208333												
5B	0	1			0	2						
6			1				I	1				
7												
0.291667												
8							1	1				
9				1								
10			2				2	2				
11							1	1				
12												
13												
14												
15												
16												
17												
18						***						
19								ν.				, , , , , , , , , , , , , , , , , , ,
20												
21											-	;
Total	0	2	3	N/A	0	5	6	6				**************************************

<sup>&</sup>lt;sup>1</sup> The representative commodities for bulb vegetable crop group are green onion and dry bulb onion.

<sup>&</sup>lt;sup>2</sup> OPPTS 860.1500 Table 5 does not identify specific regions for green onion field trials, however, trials were conducted for green onions in Regions 6 and 10, which together account for 72% of green onion production (OPPTS 860.1500, Table 6).

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BAS 510 F
Bulb Vegetable Crop Group
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PMRA a.i. code (CCH)

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Table I	2.2. Crop and Fi	Table 1.2.2. Crop and Field Trial Information.	ĵoj.								
EPA Region	Location (County, State, Year)	Crop, Variety	Formulation	Formulation Application Timing	<	Re- treatment	Number of Applications	Application Method	Total Application	Tank Mix Adjuvants	Harvest Procedures
,					(Kg ai/ha)			Volume (GPA)	(b airA)		
Onion, green	lacen.										
9	Uvalde, TX,	Green onion,	70% WG	2 leaves	0.298-0.314	13-14	9	Foliar spray/	1.82	Induce	Whole plant (without
in State Lands	6661	White		2 leaves	0.3521		**************************************	21.8-23.0	<b>3</b>	(0.25%, v.v)	roots) harvested 7
******				beginning bulbs						-	application (DALA).
				beginning bulbs							
NA THE STATE OF TH				bulbing		erita di kisikin					3
,				1" bulbs					*		
2	Tulane, C.A.	Green onion,	70% WG	1.5" tall	0.298-0.306	41	9	Poline spray/	1.8.1	Latron B-1956	Whole plant (without
		White 404		3-4" tall	0.334			29.9-30.9	[5.03]	(402/100gal)	roots) harvested 7
				3-4 leaves			^				
				5-6 leaves							
				6-7 leaves		•			-		
				8+ leaves			× .				
2	Madera, CA,	Green onton,	70% WG	onions emerging	0.299-0.311	2	9	Foliar spray/	1.83	Latron B-1956	Whole plant (without
	À	A-55 Bunching		immature onions	0.335			29.9-31.1	[502]	(pag()()/209)	roots) harvested 7
				small onions			E.				
				medium onions	<del></del>				-		
				onions maturing							
				mature onions							:

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able 1.2	2. Crop and Fix	Table 1.2.2. Crop and Field Trial Information	Ş								
. <b>2</b> 2	A Location	Crop, Variety	Formulation	Crop, Variety   Formulation   Application Timing   Application	Application	Re-	Number of	Application	Total	Tank Mix	Harvest Procedure
egion	Kegion (County, State, Year)						Applications		Application	Adjuvants	
		=				(days)		Application Volume (GPA)	(ib ai/A)		
L								[I/ha]	[kg ai/ha]		
District dry bulls	7					U-\$00			,		

Table 1.2.2. Cropp and Field Trial Information.           EPA Region Region Stale, Year)         Location Crop, Variety         Formulation Replication Triming Application Rate (Rate (	
p and Field Trial Information.  Crop. Variety Formulation Application Timing Application Recars (Ib ai/A) [Rate (Ib ai/A)]  PA. Bulb onion, 70% WG 5-14" tall 0.300-0.310 (335-0.347]  4-7 leaves [0.336-0.347]  5-8 leaves [0.336-0.347]  4-7 leaves [0.347]  T.X. Bulb onion, 70% WG 1-1" diameter 0.292-0.302 (0.327-1" diameter 0.338]  2-3" diameter 0.338]  2-3 leaves 0.300 [14-15]  Bulb onion, 70% WG 2-3 leaves 0.336]  1-1" diameter 0.336]  1-1" diameter 0.336]	
p and Field Trial Information.         Application Timing (Ib ai/A)         Application Timing (Ib ai/A)         Application Treatment (Ib ai/A)         Rear (Ib ai/A)         Rear (Ib ai/A)         Rear (Ib ai/A)         Intervals (Ib ai/A)         Application treatment (Ib ai/A)         Application Timing (Ib ai/A)         Application Timing (Ib ai/A)         Application treatment (Ib ai/A)         Application treatment (Ib ai/A)         Application treatment (Ib ai/A)         Application (Ib ai/A)         Reat           PA.         Bulb onion, Stutigarter         70% WG         5-8 leaves, anaturing         0.300-0.310         37635         37634	
P and Field Trial Information.         Application Timing (Ib ai/A)         Application Treatment (Ib ai/A)         Re- Rate (Ib ai/A) (Ib ai/A)         Reate Intervals (Ib ai/A) (Ib ai/A)         Reate Intervals (Ib ai/A) (Ib ai/A)         Rate Intervals (Ib ai/A) (Ib ai/A)         Intervals (Ib ai/A) (Ib ai/A)         Application Timing (Ib ai/A) (Ib ai/A)         Application Treatment (Ib ai/A) (Ib ai/A)         Application Treatment (Ib ai/A) (Ib ai/A)         Application Treatment (Ib ai/A) (Ib ai/A)         Application Timing (Ib ai/A) (Ib ai/A)         Application Timing (Ib ai/A) (Ib ai/A)         Application Re- Intervals (Ib ai/A) (Ib ai/A) (Ib ai/A) (Ib ai/A)         Application Re- Intervals (Ib ai/A) (Ib ai/A) (Ib ai/A) (Ib ai/A)         Application Re- Intervals (Ib ai/A) (Ib ai/A) (Ib ai/A) (Ib ai/A) (Ib ai/A)         Application Re- Intervals (Ib ai/A) (Ib ai/A) (Ib ai/A) (Ib ai/A) (Ib ai/A)         37635 (Ib ai/A) (Ib ai	
p and Field Trial Information.         Application Timing Rate (Ib ai/A)         Application Reament (Ib ai/A)         Rate (Ib ai/A)         Rate (Ib ai/A)         Reatment (Ib ai/A)         Recatment (Ib ai/A)         Rate (Ib ai/A)         Rate (Ib ai/A)         Intervals (Id ays)           PA.         Bulb onion, Stuttgarter         70% WG         3-7" tall 0.300-0.310 0.347]         37635 0.347]         37635 0.347]           -1" tall onion, Cimarron         70% WG         -1" diameter 0.392-0.302 0.347]         37634 0.327-0.338)           -1" diameter 0.338) 2-3" diameter 0.338) 2-3" diameter 0.338) 2-4" builbs 0.300 0.3415         37634 0.338)           Bulb onion, 0.70% WG         2-3 leaves 0.300 0.300 0.3415	22.9-24.5   [2.02]   (1pt/100gal)
p and Field Trial Information.  Crop, Variety Crop, Variety Formulation  Application Timing Rate (Ib al/A)	1.80
p and Field Trial Information.  Crop, Variety Formulation Application Timing Rate (the ai/A) Rate (the ai/A) Intervals (kg ai/ha] (days)  PA. Bulb onion, 70% WG 5-14" tall 0.300-0.310 (37635. 5-8 leaves 8-10 leaves.  Bulb onion, 70% WG 8-10 leaves.  TX. Bulb onion, 70% WG 1-1" diameter 0.292-0.302 (0.327-0.338)  Cimarron 2-4" diameter 0.338]  2-4" diameter 0.338]	
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p and Field Trial Information.         Application Timing Replication Timing Rate (Ib ai/A)         Application Replication Replication (Ib ai/A)         Rate (Ib ai/A)         Rate (Ib ai/A)         Rate (Ib ai/A)         Rate (Ib ai/A)         Intervals (Importance)           PA.         Bulb onion. Stuttgarter         70% WG 2-1" tall 2-14" tall 0.300-0.310         37635         37635           PA.         Stuttgarter         5-8 leaves         [0.336-0.347]         37635           8-10 leaves. maturing         8-10 leaves. maturing         0.292-0.302         37634           1" diameter         0.338]         37634	, a
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p and Field Trial Information.  Crop. Variety Rormulation Application Timing Rate (Ib ai/A) Intervals (Ib ai/ha) (Ib ai/h	,, 1.79
p and Field Trial Information.  Crop. Variety Rormulation Application Timing Rate (1b ai/A) Intervals (1b ai/ha) (days)  PA. Bulb onion. 70% WG 3-7" tall 0.300-0.310 37635  Shuttgarter 4-7 leaves 5-8 leaves 8-10 leaves  S-10 leaves 6-10 leaves 6-10 leaves	
p and Field Trial Information.  Crop. Variety Rormulation Application Timing Rate (Ib ai/A) Intervals [kg ai/ha] (days)  PA. Bulb onion. Stuttgarter Stuttgarter Stuttgarter Stuttgarter Stuttgarter State S	
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p and Field Trial Information.  Crop. Variety Rormulation Application Timing Replication Re- y, (1b ai/A) Intervals [kg ai/ha] (days)	1.82
Crop and Field Trial Information.  Crop. Variety Formulation Application Timing Application Recounty, atc, Year)  Results Formulation Application Timing Rate treatment (Ib ai/A) Intervals [kg ai/ha] (days)	
Crop and Field Trial Information.  Crop, Variety Formulation Application Timing Application Recounty,  atc, Year) (lb ai/A) Intervals	Volume (GPA) (1b ai/A) [l/ha] [kg ai/ha]
Crop and Field Trial Information.  Crop, Variety Pormulation Application Timing Application Recounty,	S.
	Application Total Tank Mix  Method Application Adjuvants

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Table 1.2.2. Crop and Field Trial Information.

EPA Region	EPA Location Region (County, State, Year)	Crop, Variety	Formulation	Formulation Application Timing	Application Rate (lb ai/A) [kg ai/ha]	Re- treatment Intervals (days)	Number of Applications	Application Method/ Application Volume (GPA) [Uha]	Total Application Rate (lb ai/A) [kg ai/ha]	Tank Mix Adjuvants	Harvest Procedures
<u>o</u>	Tulare, CA, 1999 (decline study)	Bulb onion, Red Cerole	70% WG	-1.2" bulbs -1.2" bulbs 2" bulbs 2-3" bulbs 2-3" bulbs	0.299-0.302 [0.335- 0.338]	*	•	Foliar spray/ 30.0-30.5 [336-342]	1.81 [2.03]	(402/100gal)	Bulbs harvested 0, 7, 14, 21, and 28 DALA.
9	Madera, CA, 1999	Bulb onion, Blanco Duro	70% WG	6-8" onions 5-8 leaves small bulbs medium-large bulbs	0.296-0.308 [0.332- 0.345]	4	\(\frac{1}{2}\)	Foliar spray/ 29.6-30.8 [332-345]	[2.03]	(602/100gal)	Bulbs harvested 7 DALA.
Tomas Control	Jefferson, OR, 1999	Bulb onion, Yellow Danver	70% WG	S leaves 8 leaves 12-16" tall 2.5-3" diameter 3" diameter 2-3" diameter	0.300-0.310 [0.336- 0.347]	14-15	v	Foliar spray/ 29.0-31.3 [325-351]	1.83 [2.05]	R-11 (1pV100gal)	Bulbs harvested 7 DALA.

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#### 1.3. Post-harvest Procedures

A single untreated and duplicate treated samples of green onions (whole plants without roots) and dry bulb onions were harvested from each field trial. Specific harvesting procedures were not described; however, each bulb onion sample consisted of at least 12 large bulbs or 24 small bulbs, and each green onion sample consisted of at least 24 whole plants; sample weights were ≥4.4 lbs. Additional samples of dry bulb onions were collected from the California trial (Tulare County) at various time intervals for residue decline samples. Samples were bagged and stored frozen (temperature not specified) on the day of harvest. Samples were shipped frozen within 0-22 days of harvest to BASF Agricultural Products Center (Research Triangle Park, NC) for analysis.

Table 1.3.1. Sun	mary of Storage Conditions		
Matrix	RAC	Storage Temperature ('C) at Analytical Laboratory	Duration
Onion, green	whole plant (without roots)	<-10 ° °	106-186 days ( 3.5-6.1 months)
Onion, dry bulb	bulb	< -10	78-170 days (2.6-5.6 months)

# 1.4. Analytical Methods

Samples of onion (green and dry bulb) were analyzed for residues of BAS 510 F using LC/MS/MS method D9908, the data collection method for plant commodities. Briefly, onion samples were extracted with methanol:water (70:30, v:v) and filtered. An aliquot of the filtrate was cleaned up using C18 solid phase extraction. Residues were eluted with dichloromethane. The eluate was evaporated and residues were redissolved in ammonium formate:formic acid for analysis by LC/MS/MS; refer to the DER for MRID 45405027 for a complete description of the quantitation procedures. The limit of detection (LOD) was 0.025 ppm, and the validated limit of quantitation (LOQ) was 0.050 ppm for the residues of BAS 510 F in/on green and bulb onions. The concurrent recovery results obtained are presented in Table 2.1 below.

#### 2. Results

Table 2.1. Summ	nary of Concurrent Analytical Meth	od Validation.	
Crop Matrix	Fortification Level (ppm)	Recoveries (%)	Mean Recovery ± SD
Onion, green	0.050, 1.0	85, 98, 102	95 ± 9
Onion, dry bulb	0.050, 1.0	76, 79, 88, 100	86 ± 11

Location (County, State, Year)	Crop Variety	Commodity	Formulation	Total Rate (lbs ai/A) [kg ai/ha]	PHI (days)	BAS 510 F residues (ppm)
		Onic	on, green	, , , , , , , , , , , , , , , , , , ,	gr.	
Uvalde, TX, 1999	Texas Early White	whole plant (without roots)	70% WG	1.82 [2.04]	7	2.51, 2.94
Tulare, CA, 1999	Southport White 404	whole plant (without roots)	70% WG	1.81 [2.03]	7	1.84, 2.94
Madera, CA, 1999	K-99 Bunching	whole plant (without roots)	70% WG	1.83[2.05]	7	1.06, 1.19
		Onion	, dry bulb			
Lehigh, PA, 1999	Stuttgarter	bulbs	70% WG	1.82 [2.04]	7	0.079, 0.128
Uvalde, TX, 1999	Cimarron	bulbs	70% WG	1.79[2.00]	7	0.088, 0.100
Armstrong, TX, 1999	Vega	bulbs	70% WG	1.80[2.02]	7	0.099, 0.153
Tulare, CA, 1999	Red Cerole	bulbs	70% WG	1.81[2.03]	0	0.695, 0.793
(decline study)		÷		*	7	0.185, 0.240
					14	0.054, 0.102
					21	0.083, 0.132
					28	0.110, 0.168
Madera, CA, 1999	Blanco Duro	bulbs	70% WG	1.81[2.03]	7	0.826, 1.03
Jefferson, OR, 1999	Yellow Danver	bulbs	70% WG	1.83[2.05]	7	0.026, 0.061

Commodity	Total Application Rate	PHI		Resi	idue Levels	(ppm)	-
	(lb ai/A)	(days)	Minimum	Maximum	HAFT	Mean (median)	Std. Dev
Onion, green	. 1.81-1.83	7	1.06	2.94	2.72	2.08 (2.18)	0.841
Onion, dry bulb	1. <b>79</b> -1.83	7	0.026	1.03	0.929	0.251 (0.114)	0.325

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## 3. Discussion

#### 3.1. Methods

Bulb and green onions were harvested 7 days following the last of six foliar spray applications of the 70% WG formulation at ~0.3 lb ai/A/application (0.336 kg ai/ha/application), with 13- to 15-day retreatment intervals, for a total rate of 1.79-1.83 lb ai/A (2.00-2.05 kg ai/ha). Applications were made using ground equipment in a spray volume of 21.4-31.3 gal/A (240-351 l/ha) of water with a spray adjuvant added. In one trial (Tulare County, CA), additional dry bulb onion samples were collected at 0, 7, 14, 21, and 28 days following treatment to evaluate residue decline. It was noted that the 70% BAS 510 F WG formulation used in the field trials also contained another experimental active ingredient (BAS 500 F; pyraclostrobin) as part of the tank-mix. Data for the BAS 500 F active ingredient were submitted separately.

Three green onion trials were conducted in Regions 6 (one trial) and 10 (two trials) and six dry bulb onion trials were conducted in Regions 1 (one trial), 6 (one trial), 8 (one trial), 10 (two trials), and 11 (one trial). The number and location of field trials conducted for green and dry bulb onions are in accordance with the EPA's guidance requirements (OPPTS 860.1500, Tables 2, 5, and 6). The number and location of the trials does not satisfy the PMRA data requirements (Dir 98-02). A total of four additional residue trials in dry bulb onions (2 trial carried out in zone 5 and two trials carried out in zone 5B) and 2 additional residue trial in green onions (one trial in each of 5 and 5B) are required. It should be noted that these trials are needed to support both the use of this chemical on this crop group but also to support the residue levels resulting in rotated crops from the use of this chemical in any crop.

Residues of BAS 510 F in/on onions (green and dry bulb) were quantitated using a validated LC/MS/MS method D9908, the data collection method for plant commodities. Storage stability data (refer to the DER for MRID 45405109) in five diverse matrices are available to support the storage conditions and intervals of samples from the submitted onion field trials.

## 3.2. Results

In green onions, residues of BAS 510 F were 1.06-2.94 ppm in/on samples harvested 7 days following the last of six foliar spray applications of the 70% WG formulation at 0.298-0.314 lb ai/A/application (0.334-0.352 kg ai/ha/application), for a total rate of 1.81-1.83 lb ai/A (2.03-2.05 kg ai/ha). Apparent residues of BAS 510 F were less than the method LOQ (<0.050 ppm) in/on three samples of untreated green onions. Aside from below-normal rainfall at the Texas trial site and one of the California trial sites, no abnormal weather, environmental conditions or agricultural practices were noted during the green onion field trials. Irrigation was employed at all of the green onion field trials.

In <u>dry bulb onions</u>, residues of BAS 510 F were 0.026-1.03 ppm in/on samples harvested 7 days following the last of six foliar spray applications of the 70% WG formulation at 0.292-0.310 lb ai/A/application (0.327 0.347 kg ai/ha/application), for a total rate of 1.79-1.83 lb ai/A (2.00-2.05)

kg ai/ha). Apparent residues of BAS 510 F were less than the method LOQ (<0.050 ppm) in/on six samples of untreated dry bulb onion. The residue decline data for dry bulb onion demonstrated that residues of BAS 510 F generally declined with longer posttreatment intervals. Aside from above-normal temperatures at the Pennsylvania trial site, and below-normal rainfall at one Texas trial site and one California trial site, no abnormal weather, environmental conditions or agricultural practices were noted during the dry bulb onion field trials. Irrigation was employed at all of the dry bulb onion field trials.

Residue data from the current submission are acceptable to fulfill the EPA's crop field trial data requirements for the bulb vegetable crop group (Crop Group 3). The submitted residue trials do not meet the requirements set out by the PMRA. A total of five additional trials (3 trials carried out in zone 5 and two trials carried out in zone 5B) will be needed to support a full registration.

#### 4. Deficiencies

None for US registration. The submitted residue trials do not meet the requirements set out by the PMRA. A total of five additional trials (3 trials carried out in zone 5 and two trials carried out in zone 5B) will be needed to support a full registration in Canada.

#### 5. References

45672101 Wofford, J.; et al (2002) A Summary of Weather Conditions for BAS 510 F Field Residue Studies Conducted from 1999-2001 Data: BASF Registration Document Number: 2002/5002878. Unpublished study prepared by BASF Agro Research. 24 p.